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H-7021

Automated Hematology Analyzer Operation Manual

LABOMED, Inc.

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1. Introduction

1.1 General Introduction

Hematology diagnostics is growing increasingly important as one of the most fundamental types of clinical testing. The LABOMED R&D group has been developing a variety of automatic hematology analyzers, including the H-7021. HB series is designed to meet a higher standard of clinical technology needs, capable of simultaneous determination of 19 measurement parameters with 3 histograms. All results are displayed on screen, as well as internally or externally printed, along with alarms or warnings on the test report.

1.1.1 Technical Specifications

Weight	23 Kg
Dimension	L32XW50xH42
Power Supply	AC220 (1 ± 10%) V, (50 ± 1) Hz
Working Conditions	Ambient temperature: 18°~35℃ Relative humidity: ≤ 80% RH
Storage Conditions	Atmospheric pressure: 80 kPa~106kPa Ambient temperature: 10°~40℃ Relative humidity: ≤ 80% RH
Throughput	Atmospheric pressure: 80 kPa~106kPa 60/hour
Memory	200,000 records
Designed Life	5-8 years
Dosage of Sampling	Whole blood: 13 ul Predilution: 20 ul
Dosage of Reagent	Diluent: 20ml Lyse: 0.4ml Detergent: 10ml

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1.2 Parameters

The instrument features a simultaneous determination of 19 parameters as shown in Table 1.

Table 1 19 parameters

Para	Name	Unit
WBC	Total number of WBC	10^9 cells/L
LY#	Lymphocyte	10^9 cells/L
MO#	Monocyte	10^9 cells/L
GR#	Granulocyte count	10^9 cells/L
LY%	Lymphocyte	%
MO%	Monocyte	%
GR%	Granulocyte ratio	%
RBC	Red blood cell	10^{12} cells/L
HGB	Hemoglobin	g/L
HCT	Hematocrit	%
MCV	Mean corpuscular volume	fL
MCH	Mean corpuscular hemoglobin	pg
MCHC	Mean corpuscular hemoglobin concentration	g/L
RDW-CV	Coefficient variation of RBC distribution width	%
RDW-SD	Standard deviation of RBC distribution width	fl
PLT	Platelet	10^9 cells/L
MPV	Mean platelet volume	fL
PDW	Platelet distribution width	fL
PCT	Plateletocrit	%

1.3 Front View

The front view is shown as Figure 1.

Figure 1 Front view

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①. Power indicator

Green: Instrument is ready for analysis.

Orange: Instrument is running analysis.

②. Probe

Collect sample.

③. Start

Press to run sample suction.

④. Printer

Print test result.

⑤. Keyboard

The keyboard consists of 25 keys. Functions are as follows:

"0~9": input digital.

" • ": input decimal point.

"DECLOG": de-clog.

"PRINT": start record device to print test result.

"MENU": function selection or escape.

"DILUENT": discharge diluents from probe for pre-dilution of peripheral blood.

"DELETE": delete input numbers or letters.

"CLEAN": run cleaning process.

"OK": confirm the current selection.

"ESC": press to escape the current page.

"MODE": transmission between whole blood and pre-dilution.

"↑ ↓ ← →": direction movement for selection.

⑥ Display

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The display consists of a 5.7 inch LCD monitor with 5 workspaces as Figure 2.

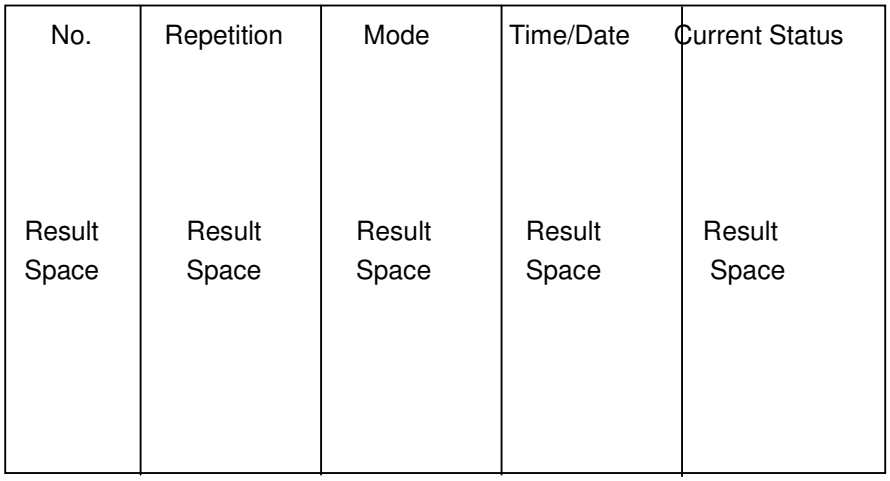

Figure 2 Display workspaces

Current status: 3 statuses

-- Show "Counting, Please wait" during count process.

-- Show counting time of WBC & RBC after counting completed.

-- Alarms if a problem happens.

Time/Date: show current system time and date.

No.: show current ID No. of the sample.

Result Space: show current test results, also produce three histograms.

Mode: show current test mode.

Repetition: perform retest and ID No. is not changed.

1.4 Back View

The back view is shown as Figure 3

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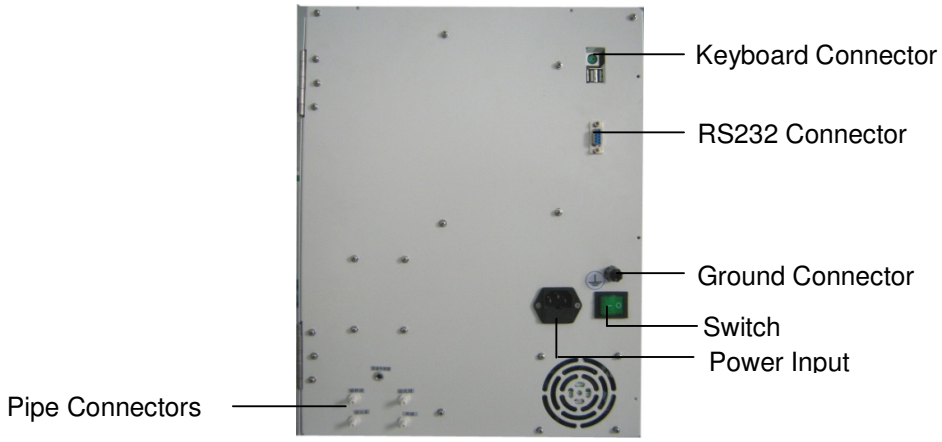

Figure 3 Back view

1.5 Components and Consumables

The main components consist of host, printer (optional) and reagents.

1.5.1 Host

The host is capable of completing the whole process of sample collection and analysis, automatically displaying test results on monitor. It mainly includes the following components:

1.5.1.1 A / D and Mainboard

The mainboard controls the following parts:

-- Status of all valves (on/off) along liquid channel, suction and perfusion of reagent and drain of waste liquid.

-- Work of pressure pump and vacuum pump, bringing drive for suction and perfusion.

-- Work of stepper motor for suction and dilution of samples and adding of reagents.

-- A /D transmission of WBC, RBC/PLT, HGB.

1.5.1.2 WBC Measurement Unit

WBC measurement unit consists of hardware including signal collection board, electrode, Millipore sensor and tubing, etc.

-- Signal collection board provides a constant electric current for electrodes,

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and provides an amplified pulse signal to CPU.

-- The unit's two electrodes, namely the internal electrode inside WBC probe and the external electrode outside. When the two electrodes are immersed in liquid mixed of diluents, the constant electric current on electrode forms a galvanic circle through the Millipore sensor.

-- The unit's Millipore sensor with a diameter of 100 microns is fixed in the front of the probe. Particles of sample pass through the Millipore in the process of measurement.

-- The tubing uses negative pressure to suck diluent, detergent and sample into each respective pipe, and then discharges the waste liquid. A lyse unit is installed in front of the tubing with the stepper motor's control to add lyse into sample cup.

1.5.1.3 RBC/PLT Measurement Unit

RBC/PLT measurement unit consists of hardware including signal collection board, electrode, Millipore sensor and tubing, etc.

-- Signal collection board provides a constant electric current for electrodes, and provides amplified pulse signal to CPU.

-- The unit's two electrodes, namely the internal electrode inside RBC/PLT probe and the external electrode outside. When the two electrodes are immersed in liquid mixed of diluents, the constant electric current on electrode forms a galvanic circle through the Millipore sensor.

-- The unit's Millipore sensor with a diameter of 80 microns is fixed in the front of the probe. Particles of sample pass through the Millipore in the process of measurement.

-- The tubing uses negative pressure to suck diluent, detergent and sample into respective pipe, and then discharges the waste liquid.

1.5.1.4 Tubing

Tubing consists of solenoid valve, pressure pump, vacuum pump and plastic pipes.

-- Solenoid valve controls the circulation of tubing.

-- Vacuum pump controls the suction of diluent into container.

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-- Discharge pump drains the waste liquid into waste container.

-- Pressure pump provides positive pressure force for washing and lyse mixing.

-- Plastic pipes provide a channel for circulation of reagent and waste liquid.

-- Vacuum chamber is a temporary waste liquid container after sample measurement.

1.5.1.5 Display

H-7021 series is equipped with a 5.7 inch LCD monitor which can display 19 parameters and three histograms.

1.5.2 Reagents

ALL REAGENTS SHOULD BE PREPARED FROM YOUR LOCAL REAGENT SUPPLIER. REAGENTS WILL NOT BE INCLUDED IN YOUR H-7021 SHIPMENT.

1.5.2.1 Diluent

Figure 4 Diluent

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Diluent can meet the test requirements as follows:

-- Dilute WBC, RBC, PLT, HGB.

-- Maintain cell shape in the process of measurement.

-- Provide proper background values.

-- Clean WBC and RBC sensor Millipore and tubing system.

1.5.2.2 Lyse

Figure 5 Lyse

Lyse is a new type reagent without double nitrogen and cyanide. It meets test requirements as follows:

-- Quickly dissolves red blood cells and produces least matrix compound.

-- Changes WBC epicyte and makes cytoplasm spread slowly.

-- Transformation of hemoglobin to form hemoglobin compound, suitable for testing under the optical wavelength of 540 nm;

-- No content of cyanide, thus avoiding pollution to humans and environment.

1.5.2.3 Detergent

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Figure 6 Detergent

Detergent contains active prolease to clean protein clogs inside pipes, mainly used for cleaning WBC and RBC probe measuring cup and test circulation.

1.5.2.4 Probe Detergent

Probe detergent contains efficient oxides to clean the probe. The detergent is mainly used for cleaning the probe.

Figure 7 Probe Detergent

1.6 Dosage of Sample

Dosage of sample is specified as Table 2.

Table 2 Dosage of sample

Mode	Type of Blood	Dosage
Whole blood	Venous blood	18ul

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Predilution	Peripheral blood	20ul

1.7 Dosage of Reagent

Dosage of reagent is specified as Table 3.

Table 3 Dosage of reagent

Type of Reagent	Dosage
Diluent	30ml
Lyse	0.7ml
Detergent	

Note: The dosage of reagent varies with the version of instrument.

1.8 Test Speed

Test speed of this instrument is about 60 / h.

1.9 Memory Capacity

The instrument has a memory inside capable of saving not less than 200,000 test results.

1.10 Repeatability Error

Measurement repeatability error is specified as Table 4.

Table 4 Specification of repeatability error

Parameter	Measuring Repeatability Error (CV/%)
WBC	≤2.0%
RBC	≤1.5%
HGB	≤1.5%
MCV	≤0.5%
PLT	≤5.0%

1.11 Accuracy

Measurement value of WBC, RBC, PLT and HGB should be in the range of control standard value of whole blood. Error rate is specified as Table 5.

Table 5 Specification of accuracy

Parameter	Error Rate
WBC	≤±4%
RBC	≤±3%

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HGB	≤±3%
MCV	≤±3%
PLT	≤±8%

1.12 Linear Range

Linear range of measurement is specified as Table 6.

Table 6 Linear range of measurement

Parameter	Range	Allowed Tolerance
WBC	0×10^9/L ~6.0×10^9/L	$\pm0.3\times10^9$/L
	6.0×10^9/L ~99.9×10^9/L	±5%
RBC	0×10^{12}/L ~0.99×10^{12}/L	$\pm0.05\times10^{12}$/ L
	1.0×10^{12} ~9.99×10^{12}/L	±5%
HGB	0 g/L ~99 g/L	±2g/L
	100 g/L ~300 g/L	±2%
PLT	0×10^9/L ~99×10^9/L	$\pm10\times10^9$/L
	100×10^9/L ~999×10^9/L	±10%

1.13 Storage and Transportation

-- ambient temperature: -10 ℃ ~ 40 ℃

-- relative humidity: ≤ 80% RH

-- atmospheric pressure: 80 kPa ~ 106kPa

1.14 Working Conditions

-- ambient temperature: 18 ℃ ~ 35 ℃

-- relative humidity: ≤ 80% RH

-- atmospheric pressure: 80 kPa ~ 106kPa

1.15 Duration of Service

The duration of service is designed to be 5 years, but not longer than 8 years.

2. Measurement Principle and Method

2.1 Measuring Principle

Measurement consists of blood cells counting and volume calculation and HGB measurement.

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2.1.1 Impedance

The instrument adopts the method of impedance to measure and count cells.

As shown in Figure 8, the conductive liquid (mainly diluent) provides constant current source to the electrode, thus the circuit can form a steady impedance circulation. When cells pass through the Millipore, the conductive liquid is replaced by cells. Change of circuit resistance produces an electrical pulse. The amplitude varies when cells of different size pass through the Millipore. Consequently, the number and volume of cells passing through the Millipore can be calculated based on the amplitude.

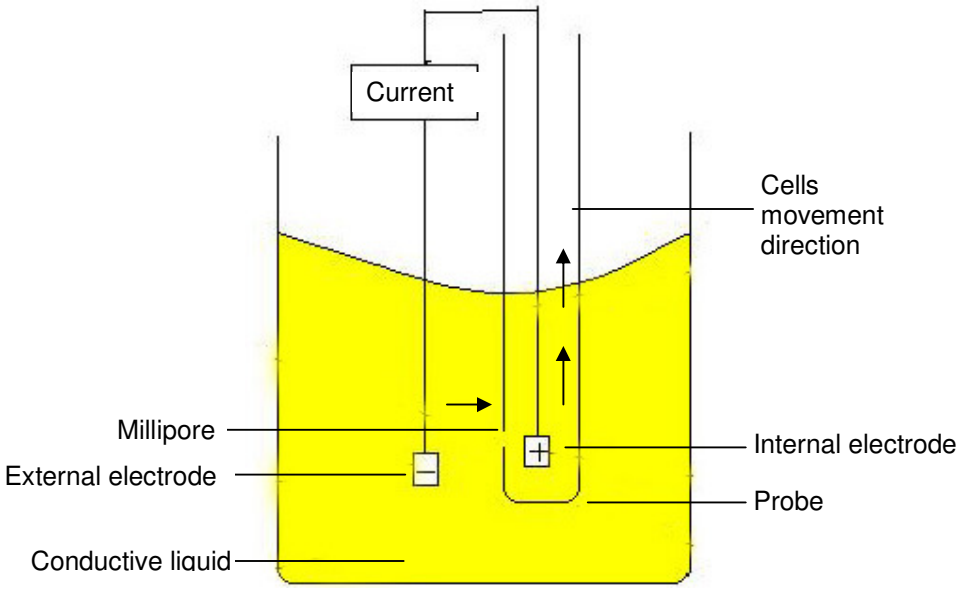

Figure 8 Process of measurement

As the number of pulses is corresponding with the cells which pass through the Millipore, amplitude of pulse has the same size with the cells. The instrument measures each of the cells, and classifies them with regard to their volume as RBC, WBC and PLT. Normally the classification standard is shown as Table 7.

Table 7 Blood classification standard

Type of Cells	Standard
WBC	35-450fl

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RBC	30-100fl
PLT	2-30fl

The WBC dealt with lyse can be classified as lymphocytes (LY), MO, granulocyte (GR) in accordance with its size. The classification standard is shown as Table 8.

Table 8 WBC classification standard

Type of Cells	Standard
LY	35-98fl
MO	98-135fl
GR	135-450fl

2.1.2 Flow Colorimetry for HGB Measurement

After mixed with blood sample, lyse can quickly destroy the cell membrane and combines with the hemoglobin to shape a compound which has an absorption characteristic of a wavelength of 540 nm. Comparison between the absorbance of diluent and blood sample can work out the concentration of hemoglobin.

2.2 Method of Calculation

Measurement values of blood sample consist of three forms: the values directly obtained from measurement, such as WBC, RBC, PLT, HGB, MCV; the values obtained from histogram, such as LY%, MO%, GR%, HCT, RDW-CV, RDW-SD, MPV, PDW; the values obtained from certain formulas, such as LY #, MO #, GR #, MCH, MCHC, PCT.

Formulas are as follows:

HCT（%）= RBC×MCV/10

MCH（pg）= 10×HGB/RBC

MCHC（g/L）= 100×HGB/HCT

PCT（%）=PLT×MPV/10

LY（%）= 100×AL /（AL+AM+AG）

MO（%）= 100×AM /（AL+AM+AG）

GR（%）= 100×AG/（AL+AM+AG）

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Histogram of WBC is shown as Figure 9

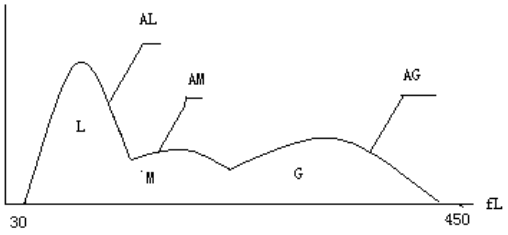

Figure 9 Histogram of WBC

Where,

-- AL: cells quantity within the lymphatic sector;

-- AM: cells quantity within the monocytes cells sector between lymphocyte and granulocyte;

-- AG: cells quantity within the granulocyte sector.

Calculation methods of absolute value of Lymphocyte LY #, monocyte MO #, granulocyte GR # are as follows:

Lymphocyte（10^9L） LY# = LY%×WBC/100

Monocyte（10^9L） MO# = MO%×WBC/100

Granulocyte（10^9L） GR# = GR%×WBC /100

RDW-CV (%) is calculated from RBC histogram. It indicates the volume distribution coefficient variation of RBC.

RDW-SD (fl) is calculated from RBC histogram. It indicates the size standard deviation of RBC.

PDW is calculated from PLT histogram. It indicates the volume distribution of PLT group.

3. Installation and Sample Analysis

To ensure good performance and satisfactory clinical work, H-7021 series must be installed and debugged first by engineers authorized by LABOMED. The installation and operation have to be performed in accordance with this instruction.

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Warning: The installation done by any unauthorized or unprofessional personnel may lead to damage. Such damages are not in the scope of free warranty, thus this execution is forbidden.

3.1 Unpack and Check Contents

-- Carefully take out of the instrument, and save the packing materials.

-- Check the accessories with respect to packing list.

-- Check to see if there's any water logging.

-- Check if there's any mechanical breakage.

-- Check all exposed wires, inserted parts and accessories. If there are any problems, please contact customer service or agent.

3.2 Installation Requirements

Please refer to part 10.2.

Warning:

-- Home use is forbidden.

-- The instrument is used for treatment.

-- The instrument has to avoid direct sunlight.

-- The instrument has to avoid over-cooling and over-heating.

-- The instrument has to avoid centrifuge, X-ray, monitors and copiers and any device which may lead to result errors.

-- Do not use mobile phone or wireless telephone near the instrument. Strong radiation may affect the work of the instrument.

3.3 Power Source

Power source has to be checked before the installation to see if the power conforms to requirements. Details are as follows:

-- Voltage: AC220 (1 ± 10%) V

-- Frequency: (50 ± 1) Hz

Note:

--The instrument must be well grounded and connected.

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-- The plugs have to be checked before power connection.

-- The voltage of power has to be stable.

-- Power has to be constantly provided, otherwise may lead to deficiency or breakage of the instrument.

3.4 Installation of Tubing

The back panel has four pipe connectors. These connectors are covered for the purpose of pollution protection before the products leave the factory. They have to be dragged out and saved before the first installation.

3.4.1 Installation of Lyse Pipe

Take out the lyse pipe with red label from reagent box and insert into the connector labeled LYSE on the back panel, and then insert the other end into the lyse container and tightly cover the container. Make sure the lyse container is placed on the same surface as the instrument.

3.4.2 Installation of Diluent Pipe

Take the diluent pipe with blue label out of the reagent box, insert into the connector labeled DILUENT on the back panel, and then insert the other end into the diluent container and tightly cover the container. Make sure the diluent container is placed on the same surface as the instrument.

3.4.3 Installation of Waste Pipe

Take the waste pipe with black label out of reagent box, insert into the connector labeled WASTE on the back panel and connect BNC plug with the socket marked “SENSOR” on the back panel. Make sure the waste container is placed at least 50cm lower than the place surface of instrument.

3.4.4 Installation of Detergent Pipe

Take the detergent pipe with yellow label out of reagent box, insert into the connector marked “DETERGENT” on the back panel, and then insert the other end into detergent container and tightly cover the container. Make sure the detergent container is placed on the same surface as the instrument.

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Note:

-- Make sure all pipes are in natural state after installation, avoiding distortions and puckers.

-- All pipes have to be installed manually. Tools interference is forbidden.

-- For any damage or leakage or expiration of the reagents, please contact LABOMED local office or its customer service.

Warning: The waste must be handled with biochemical or chemical methods before pouring into drainage, otherwise it will cause contamination to the environment.

3.5 Installation of Paper Roll

Please refer to **Part 9.3.11**

3.6 Installation of Printer

The installation of printer is optional. If the installation is considered to be necessary, installation work can be carried out as follows:

-- Place the printer on a suitable surface. The recommended position is a distance of at least 30cm from right side of the instrument.

-- Install printer's accessories in accordance with its manual.

-- Connect printer's cable with the USB connector marked "PRINTER" on the instrument back panel.

-- Be sure the printer power switch is OFF before power connection.

-- Install ink cartridge and selenium drum

-- Install printing paper as per manual instructions.

Note: Turn on printer before the instrument.

3.7 Power Connection

Make sure the power switch on the back panel is off (O), and then connect the instrument with electricity socket by the wire.

Note: The wire has to be connected to a special electricity socket.

3.8 Startup

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Turn on the power switch on the back panel and the indicator shows red light. Then the instrument initializes test program. At the same time diluent, lyse and detergent will be sucked and tubing system cleaned. If initialization is finished, the display shows as Figure 10. Under this page the ID number of sample can be altered. Method is as follows:

-- Shift ↑↓to select “ID”, and then press OK. The display shows as Figure 11.

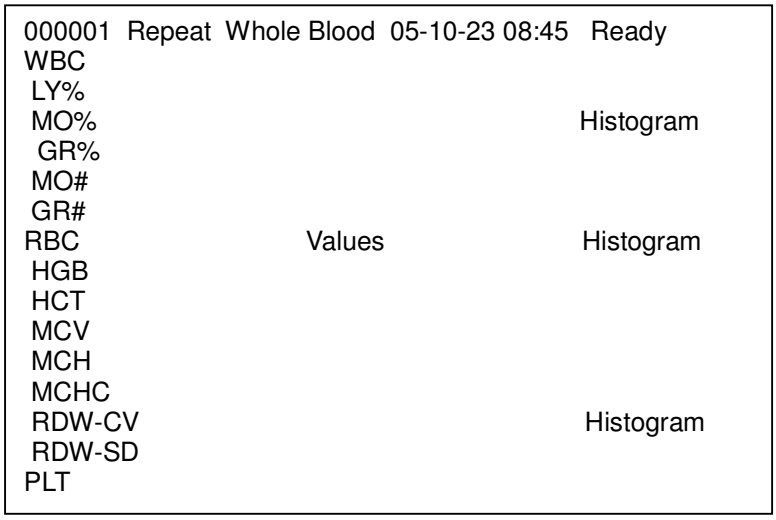

Figure 10 Blood analysis page

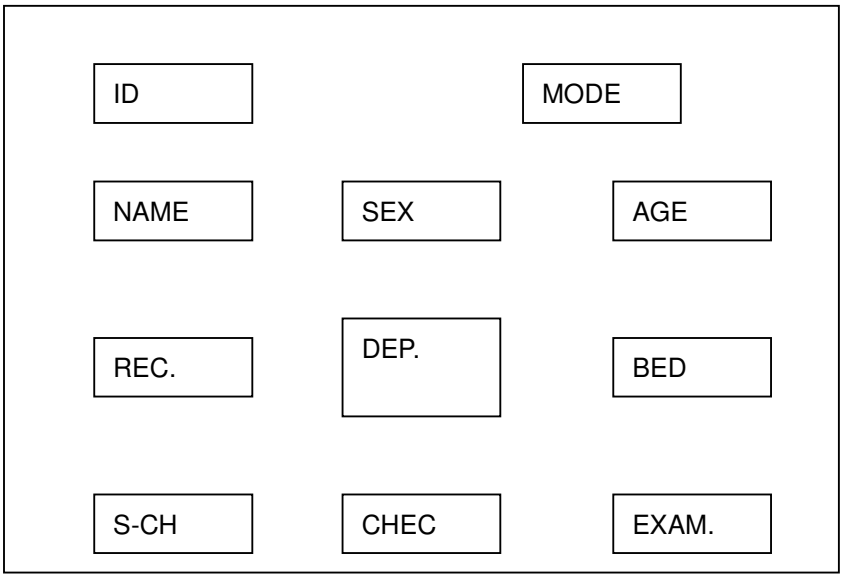

Figure 11 ID setup

-- Shift ← → to set up every item.

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3.9 Background Test

Due to the advanced technology used in this instrument, the background test has become just a one step operation, even though the step has to be performed after startup or before sample test. The operation is just to press the RUN button on the front panel.

The result range of background test is shown as Table 9.

Table 9 Acceptable value range

Type	Value	Unit
WBC	≤ 0.3	10^9/L
RBC	≤ 0.03	10^{12}/L
PLT	≤ 10	10^9/L
HGB	≤ 2	g/L
HCT	≤ 0.5	%

If obtained values are out of this range, repeat the above step until they are acceptable. Refer to part **9 Troubleshooting** if repetitions fail 5 times.

Note:

-- ID No. for background test is set to 0 by the software, whose test result will not be stored.

-- The ID No. for blood sample test cannot be set to 0.

3.10 Quality Control

Quality control should be performed after initial installation or before daily tests. Please refer to Part **5 Quality Control.**

3.11 Calibration

The instrument is strictly tested before leaving the factory. There is no need to recalibrate the instrument if the results of background test and quality control are normal. However, if the results are not satisfactory and if some parameters deviate, recalibration can be performed as per part **6 Calibration**.

3.12 Collection of Blood Sample

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Note:

-- Clinical samples, controls and calibrators may contain human blood or serum, thus these materials may be a source of infection. The disposal work has to be done as per laboratory regulations or clinical procedures.

-- Blood collection and disposal has to be performed as per municipal or laboratory requirements.

-- Be sure the collected blood is clean. Qualified anticoagulant is necessary.

-- Do not violently shake the test tube.

-- Venous blood can be stored for only 4 hours at room temperature. It is recommended that the blood sample be stored at a temperature between 2-8℃ if it is not possible to finish the test in short time.

3.12.1 Collection of Whole Blood

The collected whole blood has to be mixed with anticoagulant EDTA-K2·$2H_2O$ in a clean test tube. The anticoagulant can keep configuration of WBC, RBC and prevents platelets from congregating. Gently shake the tube 5-10 times to have it well mixed.

3.12.2 Collection of Peripheral Blood

Generally speaking, fingertip puncturing is a normal method to collect peripheral blood. The volume of blood collection tube is set to be 20ul.

Note:

-- Precision and repeatability of instrument is not only affected by quality of reagent and instrument, but to a big extent by the operation and professional level of the doctors.

-- Do not pinch the puncturing to collect blood sample for avoiding mixing of tissue fluid and blood.

-- Collection dosage has to be set to 20ul to avoid incorrect results due to blood insufficiency.

3.13 Switch of Mode

Shown as Figure 12, the current mode is Whole Blood.

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000006 repeat whole Blood Time/Date Ready

Figure 12 An example of mode switch

Shift ← → to select Whole Blood, and then press OK. The system will send a dialogue “Switch to Diluent Mode?” Press OK. Now the switch step is finished.

Switch from Diluent mode to Whole Blood mode is the same as above.

3.14 Blood Counting and Analysis

3.14.1 Counting and Analysis Process

Blood counting and analysis has to be quickly performed after collection. The suggested time is 3-5 minutes.

Diluent Mode

-- Put an empty tube under the probe and then press DILUENT. A certain dosage of diluent will be discharged into the tube. Remove the tube.

-- Add 20ul blood sample into the tube and then gently shake the tube to have it well mixed.

-- Put the tube under the probe again (The probe has to reach tube bottom). Press **Start** button on the front panel and the indicator shows red light. Only remove the tube after buzzer gives “Di”.

-- The status in the display shows Counting. Now please wait for the result.

Whole Blood Mode

-- Gently shake sample tube to mix the blood, and then put the tube under the probe (The probe has to reach tube bottom). Press **Start** button on the front panel and the indicator shows a red light. Only remove the tube after buzzer gives “Di”.

-- The status in the display shows Counting. Now please wait for the result.

The test results will be displayed together with relative histograms of WBC, RBC and PLT.

If problems like clogs or bubbles occur during the counting and analysis process, the steps will automatically stop and the instrument will send an alarm. Now the indicator shows a green light and the test results are invalid.

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For solutions, please refer to Part **9 Troubleshooting**.

If test results are out of range, L or H will appear in front of results. L means low and H high.

If the results show ***, it indicates values are invalid.

Note:

-- Make sure the mode is set correctly (whole blood or diluent) as per part 3.13.

-- Under the diluent mode, the sample can be retested if necessary.

-- Only disposable tube and fixed dosage collector can be used for preventing cross-infection.

-- According to clinical requirement, the work temperature has to be 18 ℃~35℃.

-- For doubtful sample, classified retests can be performed.

3.14.2 Histogram Alarm Message

If some blood cells are immature, abnormal or untypical, warnings can be read in histograms. Warning type like R1, R2, R3, R4, RM or PM will be displayed on the right of histograms.

3.14.2.1 WBC Histogram Alarm

R1，R2，R3，R4 or RM in WBC histogram means as follows:

-- R1: left area of lymphocyte is abnormal.

Probable causes:

Lysing is not enough and RBC exists, aggregation of platelet, bigger platelet, plasmodium, abnormal lymphocytes, condensed globins and lipid particles, etc.

-- R2: area between lymphocyte and monocyte is abnormal.

Probable causes:

Abnormal lymphocytes, plasma cells, more eosinophilic granulocyte basophilic granulocytes, etc.

-- R3: area between monocyte and granulocyte cell is abnormal.

Probable causes:

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Existence of Immature granulocytes, abnormal cells, eosinophilic granulocytes.

-- R4: right area of granulocyte is abnormal.

Probable causes：Increased granulocytes.

-- RM: the divisions of WBC excluding above areas are abnormal.

Probable cause：Above causes

3.14.2.2 Alarm on PLT Histogram

If PLT histogram is unusual, Pm alarm can be read on its right side. Pm means section between platelet and RBC is abnormal.

Probable causes: aggregation of platelets, bigger platelets, smaller RBC and existence of cell debris and fibrin.

3.15 Report Output

Print mode of the instrument is optional. The instrument system provides 2 modes: Auto print or Manual print.

Printer can be selected. The instrument system provides 3 selections: internal printer, external printer or internal & external printers.

Steps: MENU---System Setup---Printer---OK

3.16 Shut down

Before the instrument is turned off, maintenance and tubing cleaning will be automatically performed. It is required that no protein clogs exist inside the tubing system. Steps are as follows:

-- Press MENU then select 9: Shut down. Press OK, the display shows as Figure 13.

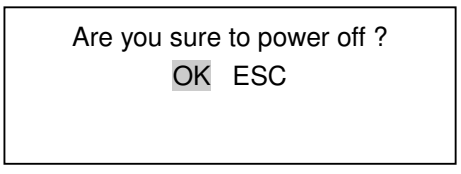

Figure 13 Shut down the instrument

-- Press OK. The display shows as Figure 14.

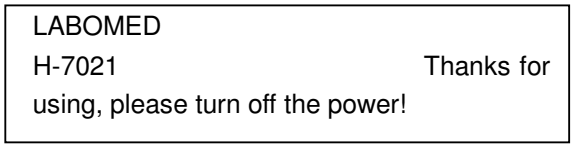

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Figure 14 Shut down the instrument

-- Tidy the work platform and dispose of waste liquid.

-- Press ESC if the user does not want to turn off the instrument. The system will return to blood analysis page.

Note:

-- Do not shut down the instrument without following this instruction, which will decrease reliability and performance of the instrument. Any problem derived from this is not in the range of LABOMED guarantee list.

-- Wrong shut down process may lead to data loss or system operation failure.

-- If the instrument is not shut down properly, the system does not clean the tubing, which may lead to a clog inside the tubing.

3.17 Result Review

3.17.1 Historical Data

User can review the values and histograms of tested blood sample, and even print out these data. Details are as follows:

-- Under blood analysis page press MENU, and then select “Data Review”. The system provides 3 methods for the review shown as Figure 15.

1. Query by name
2. Query by date
3. Query by number
4. Delete database

Figure 15 Methods of data review

3.17.2 Deletion of Old Data

When the saved data is reaching the memory, it will take longer time to review the data. If necessary, all of saved data can be deleted periodically.

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The system has 2 delete modes: clear database or delete by date.

3.17.2.1 Clear Database

When saving reaches 500,000 the system will send alarm “Memory full, please backup”, hereafter. At this time, there is still some memory left for 50 results, after which all data will be deleted automatically. Thus, if necessary, user should backup these data before they are fully deleted. Steps are as follows:

-- Under blood analysis page, press MENU, and then select “Data Review”.

-- Choose 4 Delete database and then press OK. Now the display shows as Figure 16.

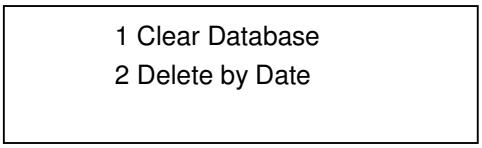

Figure 16 Methods of data deletion

-- Select 1 to clear the database.

3.17.2.2 Delete by Date

Shown as Figure 16, another method to delete data is select 2 Delete by Date.

User can input a specific date to delete all data before that date. The date format has to be the same as the format that user chooses in this system. Steps are as follows:

-- Under step shown as Figure 16, choose 2 Delete by Date.

-- Input date 12012006 (for example, the date format is MM/DD/YYYY) and then press OK.

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4. MENU

Under Blood Analysis page press MENU. The display shows as Figure 17.

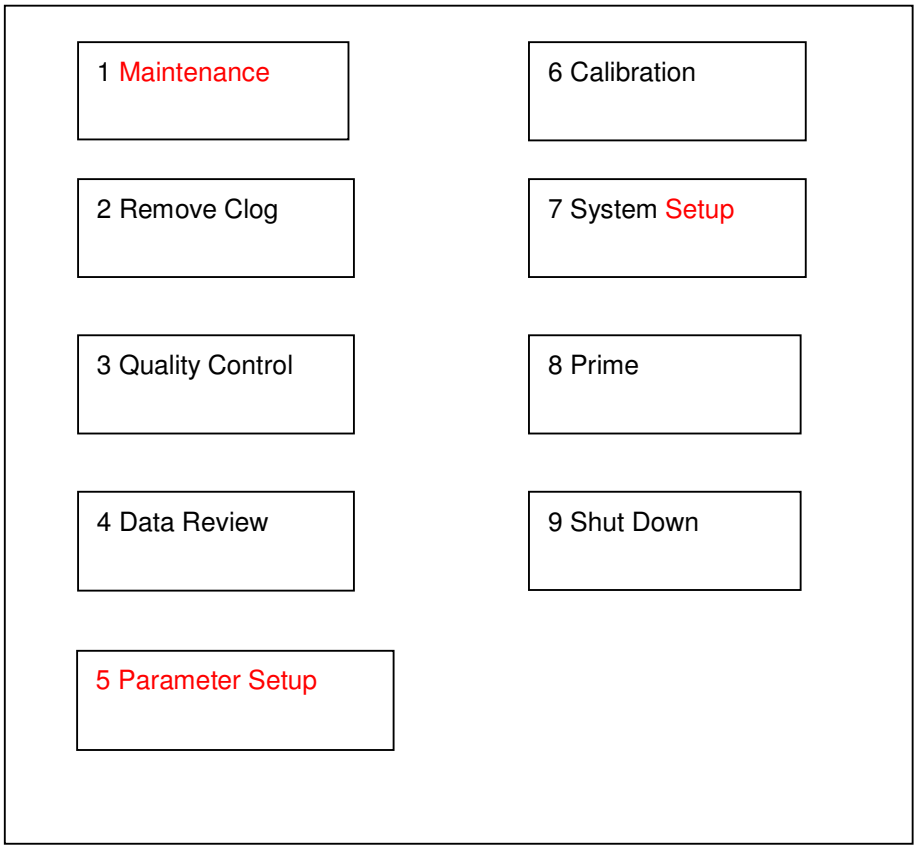

Figure 17 Main menu

Note: Changes in the menu may lead to parameter difference of the system, thus changes only when necessary.

4.1 Maintenance Menu

As shown in Figure 17, select Maintenance. The maintenance is divided into three types, namely “Daily Maintenance”, ”Weekly Maintenance" and "Yearly Maintenance" shown as Figure 18:

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1. Daily Maintenance	6. RBC Tube Drain
2. Weekly Maintenance	7. RBC Tube Circuit
3. Yearly Maintenance	8.Check Measure Time
4. WBC Tube Drain	
5. WBC Tube Circuit	

Figure 18. Maintenance Menu

4.2 Remove Clog

De-clog is an operation to remove clogs inside tubing system. Shown as Figure 17, if 2 Remove Clog is selected, the system will automatically perform the cleaning operation.

Attention: The ID No. should not be 000000, for this ID can't be saved.

4.3 Quality Control

Please refer to part **6 Quality control**

4.4 Data Review

User can review sample's values and histograms or even print them out. If necessary, users can also delete the database or data before some data.

Please refer to part **3.17**

4.5 Parameter Setup

The system realizes normal range setup of 19 parameters. If one result value is out of the normal range, an "H" will be marked besides the value indicating the value is higher than the range. If "L", that indicates the result value is lower than the range.

As shown in Figure 17, if 5 Normal Range Input is selected, the display shows as Figure 19.

1. General Limits	6. Cat Limits
2. Male Limits	7. Chicken Limits
3. Female Limits	8. Other Limits
4. Child Limits	9. Other Limits
5. Dog Limits	10. Other Limits

F

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Figure 19 Normal range input

The system default is General Limits. User can select or set other limits if it needs.

4.6 Calibration

Please refer to part **6 Calibration**.

4.7 System Setup

As shown in Figure 17, if 7 System Setup is selected, the display shows:

1. Printer Setup	8. Report Format
2. Standby Setup	9. Brightness Setup
3. Hospital Name	10. Cells Setup
4. Alarm Setup	11. Time/date Setup
5. Result Magnification	12. Upload Setup
6. Classification	13. Unit Setup
7. Cleaning Setup	

Figure 20 System setup

4.7.1 Printer

Please refer to part 3.15

4.7.2 Backlight Time

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As shown in Figure 20, if 3 Backlight Time is selected, the display shows:

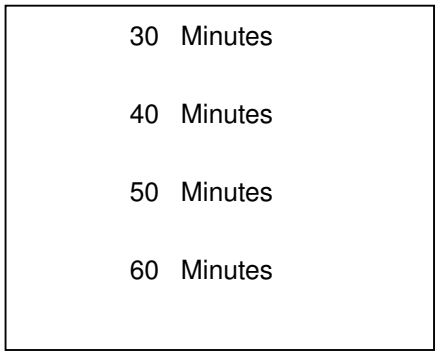

Figure 21 Backlight time setup

The backlight time is optional according to needs.

4.7.3 Hospital Name

User can edit or add hospital names into the system. The name is also printed out on test report.

As shown in Figure 20, select 3 Hospital Name, the display shows:

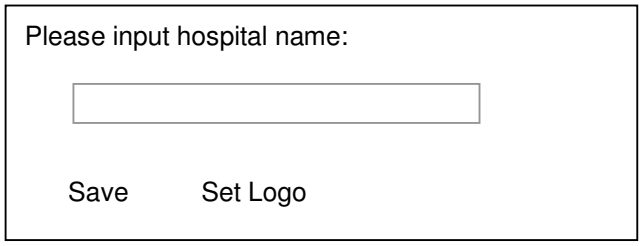

Figure 22 Setup of hospital name

4.7.4 Alarm

The system can send alarms if reagent is not enough or the waste container is full. However, the alarms are optional as shown in Figure 23. The selected sensor will be marked with an × in front.

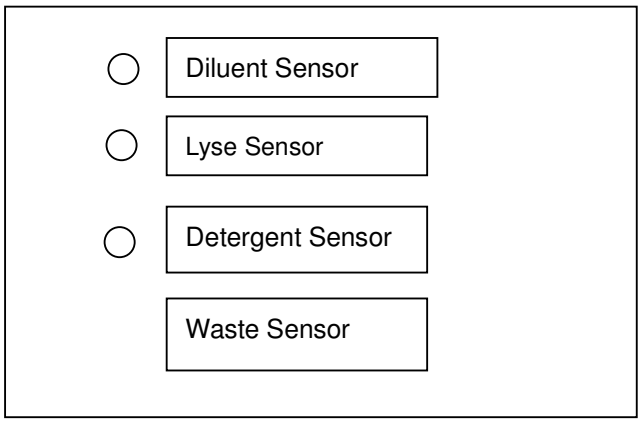

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Figure 23 Alarm Setup

4.7.5 Result Magnification

This is only necessary for testing on animals when the result needs to be magnified.

4.7.6 Classification

The system provides an alternative classification method, namely manual or automatic.

As shown in Figure 20, select 6 Classification, the display shows:

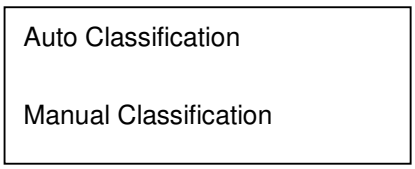

Figure 24 Classification setup

4.7.7 Cleaning Time

The system provides 2 methods to set the cleaning time, namely time or times as shown in Figure 25.

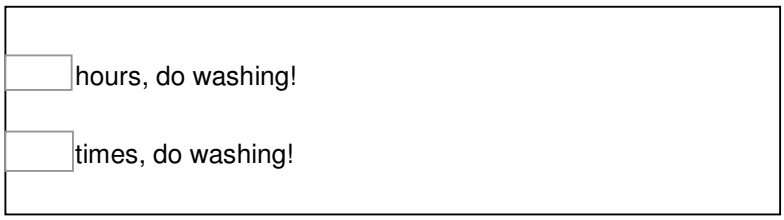

Figure 25 Cleaning time setup

4.7.8 Report Format

The system provides 6 report formats as shown in Figure 26.

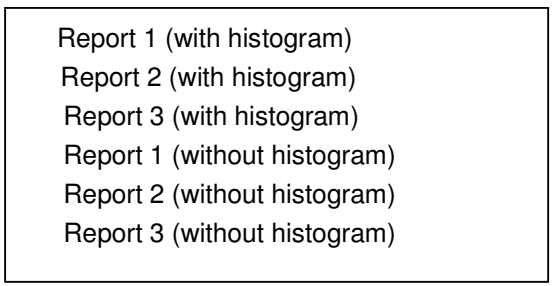
Report 1 (with histogram)
Report 2 (with histogram)
Report 3 (with histogram)
Report 1 (without histogram)
Report 2 (without histogram)
Report 3 (without histogram)

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Figure 26 Report format setup

4.7.9 Display Brightness

The display brightness is adjustable. As shown in Figure 27, user can use → ← to obtain more or less brightness.

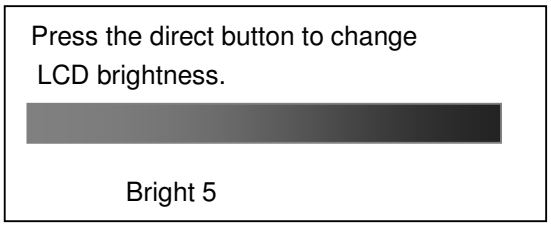

Figure 27 Display brightness

4.7.10 Determination of Cells

The diameter of cell is normally different. In this system only the cell whose diameter is in the set range will be recorded as a cell. Figure 28 presents an example.

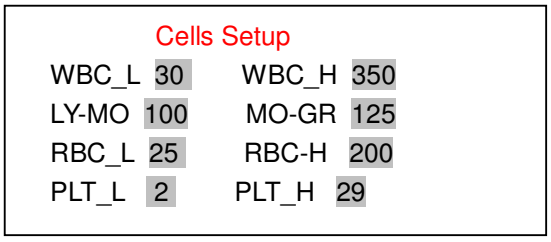

Figure 28 Determination of cells

Where,

L: minimum diameter for cells determination

H: maximum diameter for cells determination.

4.7.11 Time/Date

As shown in Figure 20, select 11 Time/Date, the display shows:

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Figure 29 Time/Date setup

The system provides 3 time/date formats as follows:

-- Year/Month/Day

-- Month/Day/Year

--Day/Month/Year

User can choose a desirable format and set up a correct time and date.

4.7.12 Update

As shown Figure 20, select 12 Upload, the display shows:

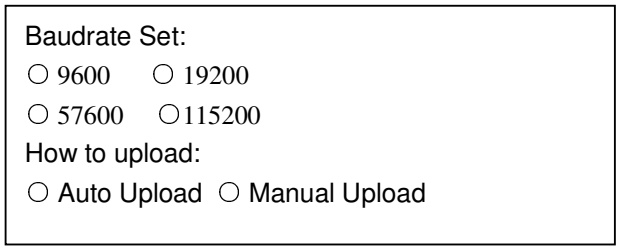

Figure 30 Upload setup

Data in the system can be uploaded into computer through the RS232 connector in the back panel of the instrument. User can select a proper baud rate according to needs.

4.7.13 Unit

As shown in Figure 20, select 13 Unit, the display shows:

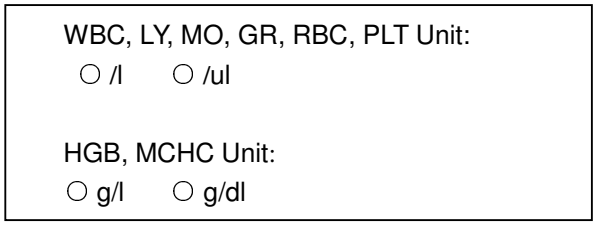

Figure 31 Unit setup

User can select a desirable unit according to needs.

4.8 Prime

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Normally the system automatically primes the tubing when startup. If user finds reagent is not enough, priming has to be performed manually. As shown in Figure 17, select 8 Prime, the display shows:

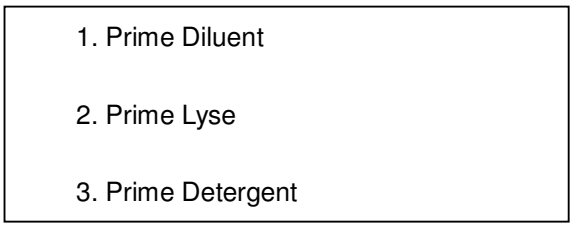

Figure 32 Prime reagent

User can select a reagent to prime, if needed.

4.9 Shutdown

Please refer to part **3.16 Shut down**

5. Quality Control

To ensure precision and accuracy of the instrument, quality control (QC) is required for the system. It is recommended that QC process should be performed under the following conditions with the QC material introduced by LABOMED:

-- After startup.

-- After reagent replacement.

-- After calibration.

-- After maintenance, repair or part replacement.

-- Required by clinical or laboratory QC regulations.

5.1 Controller

Notes for the usage of controller:

-- Store the controller as per storage stipulations. The desirable place is the middle part of refrigerator.

-- Check the status of controller and ensure of no crack and breakage on its container.

-- Follow the user's guide of the controller. Mix and warm it up slowly.

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-- Check its expiry date. Use of any expired product is prohibited.

-- Intensive heat or violent shake is prohibited.

Warning:

Clinical samples, controls and calibrators may contain human blood or serum, thus these materials may be source of infection. The disposal work has to be done as per laboratory regulations or clinical procedures.

5.2 Method

5.2.1 Preparation

The QC preparation steps are as follows:

a) Under Blood analysis page, press MENU and choose 3 Quality Control. Press OK and the display is shown as Figure 33.

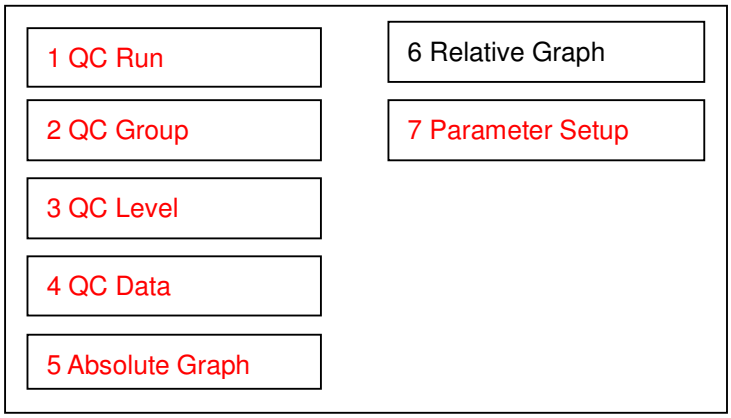

Figure 33 QC menu

b) Select 2 Group of Controller and press OK. The display shows as Figure 34.

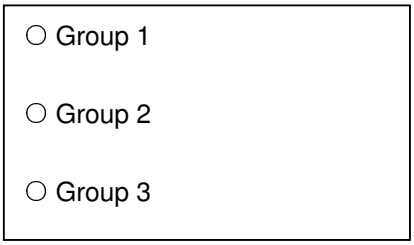

Figure 34 Group of controller

To get an accurate QC result, user has to prepare controllers of 3 different manufacturers who are divided as Group1, Group2 and Group3.

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Select Group1 and press ESC.

c) Select 3 Level of Controller and the display show as Figure 35.

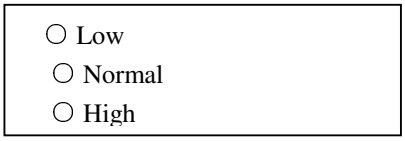

Figure 35 Levels of controller

The controller is not single. It consists of 3 levels, namely Low, Middle and High. These 3 levels have to be performed one by one.

For example, first, user can select the Low controller.

The selection will be saved by pressing ESC.

d) This step will go to 7 Input Standard Values. The display shows as Figure 36.

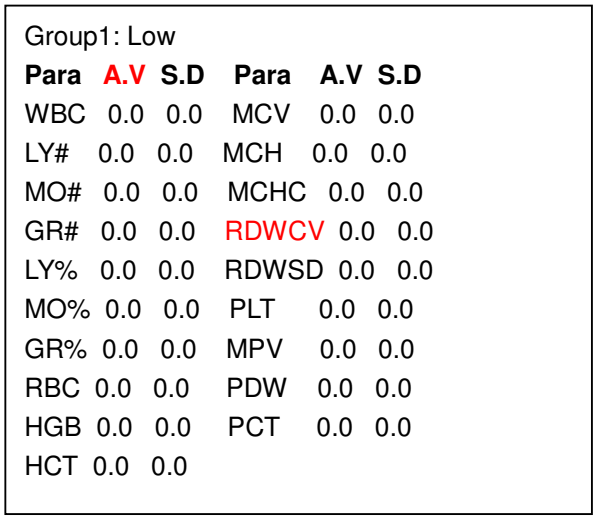
Group1: Low
Para A.V S.D Para A.V S.D
WBC 0.0 0.0 MCV 0.0 0.0
LY# 0.0 0.0 MCH 0.0 0.0
MO# 0.0 0.0 MCHC 0.0 0.0
GR# 0.0 0.0 RDWCV 0.0 0.0
LY% 0.0 0.0 RDWSD 0.0 0.0
MO% 0.0 0.0 PLT 0.0 0.0
GR% 0.0 0.0 MPV 0.0 0.0
RBC 0.0 0.0 PDW 0.0 0.0
HGB 0.0 0.0 PCT 0.0 0.0
HCT 0.0 0.0

Figure 36 Input standard values

Where,

A.V: average value

S.D: standard deviation

The manufacturer of controller always provides a *Standard Values List* for every level of controller. For example, a manufacture may provide a *Standard Values List* for low level controller shown as Figure 37.

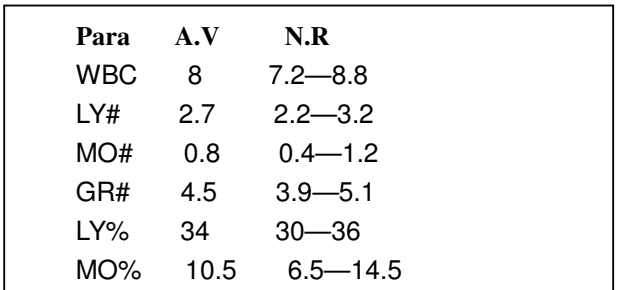

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Figure 37 Standard values list

Where,

N.R: normal range.

When the *Standard Values List* of low level controller shown as Figure 37 is in hand, user can input every A.V into the respective column shown as Figure 36. Take WBC as an example, its A.V in the list is 8, thus input an “8” into WBC’s A.V column.

How to obtain S.D?

As shown in the list, N.R of WBC is from 7.2 to 8.8, thus its S.D is 8.8-7.2=1.6. Input a “1.6” into WBC’s S.D column.

Now the display is shown as Figure 38.

Group1: Low

Para	**A.V**	**S.D**	**Para**	**A.V**	**S.D**
WBC	**8**	**1.6**	MCV	0.0	0.0
LY#	0.0	0.0	MCH	0.0	0.0
MO#	0.0	0.0	MCHC	0.0	0.0
GR#	0.0	0.0	RDWCV	0.0	0.0
LY%	0.0	0.0	RDWSD	0.0	0.0
MO%	0.0	0.0	PLT	0.0	0.0
GR%	0.0	0.0	MPV	0.0	0.0
RBC	0.0	0.0	PDW	0.0	0.0
HGB	0.0	0.0	PCT	0.0	0.0
HCT	0.0	0.0			

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Figure 38 Input of WBC A.V and S.D

e) Input values of all other parameters into their respective columns.

Method of input:

-- As shown in Figure 36, press the direction button to choose a parameter.

-- Press OK to input A.V.

-- Press OK again to input S.D.

-- Press OK to return to parameter selection.

5.2.2 Start

As shown in Figure 33, select 1 Start. The following steps are as same as part **3.14 Blood Counting and Analysis**. The result will be saved and can be read from 4 Test Result shown as Figure 39.

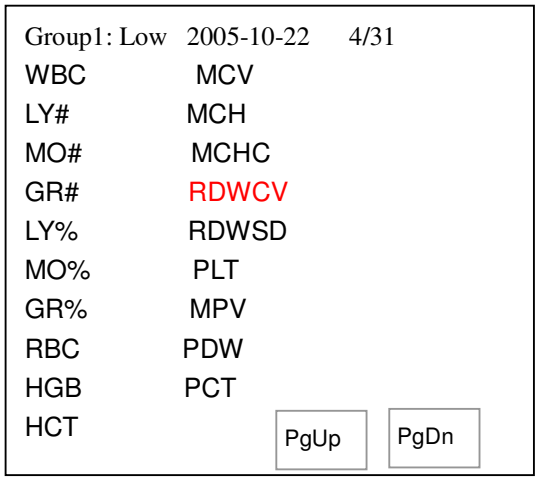

Figure 39 QC test result

31 pages can be saved. Press OK to previous page or next page. The Figure presents the 4th page.

5.2.3 QC Graphs

The system can work out 2 QC graphs, namely absolute graph and relative

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graph.

The absolute graph is made according to the standard values while the relative graph is made, according to test results.

A comparison between these 2 graphs can determine if the system needs to be calibrated.

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6. Calibration

If QC indicates that the test result deviates out of the normal range, the system needs to be calibrated. Generally the system has to be calibrated in the following situations:

-- great changes of working conditions.

-- results deviation of one or more parameters.

-- replacement of result-effected component.

-- requirement of the clinic or the laboratory.

-- replacement of reagent.

Warning: Before obtaining accurate results, all test data must not be used in clinic or laboratory.

6.1 Background Test

Background test has to be performed before calibration to ensure that the instrument doesn't have any problem. Please refer to part **3.9 Background Test.** The test has to be performed 4 times. Only results of these tests are in the ranges stipulated in Table 10 can calibration be performed.

Table 10 Error rate of background test

Parameter	Error（%）
WBC	≤±4
RBC	≤±3
HGB	≤±3
MCV	≤±3
PLT	≤±8

Take WBC as an example, the error rate is calculated as formula:

$$\frac{V_{max} - V_{min}}{A.V}$$

Where,

Vmax: the maximum value of the 4 tests

Vmin: the minimum value of the 4 tests.

A.V: the average value of the 4 tests.

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6.2 Calibration Rate

Press MENU and select 6 Calibration. The display shows as Figure 40.

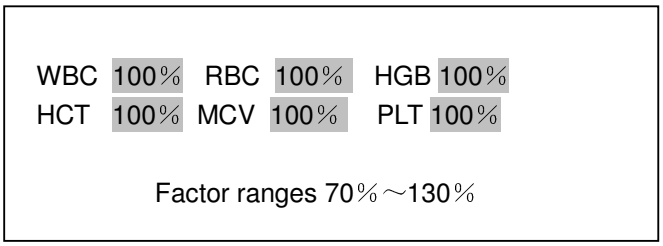

Figure 40 Calibration rate

The calibration rate is obtained from QC. Take WBC as an example, its average value of the low level controller is 8. However, the result value is only 6 which is obviously out of the normal range. Consequently, the calibration rate of WBC can be calculated through: 8/6× 100%= 133% Then input “133” into WBC column

7. Normal Range Setup

The system realizes range setup of 19 parameters. If one result value is out of the set range, an “H” will be marked besides the value indicating the value is higher than the range. If “L”, that indicates the result value is lower than the range.

Warning: Normal range is an important reference clinic diagnosis. Only change these ranges when necessary.

Steps are as follows:

-- For access the Normal Range menu please refer to part **4.5**

-- Select an item, for example Female, and then press OK and input the high and low ranges.

-- Press OK to save the input values and ESC.

8. Maintenance

8.1 Daily Maintenance

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8.1.1 Clean When Startup

The system automatically primes the reagents on startup. There is also a cleaning step in this process. In order to reduce clog, the system provides two methods to clean the tubing. Details please refer to part **4.7.7**.

Also user can perform manual cleaning if needs. Steps are as follows:

Press MENU and select Prime, and then press OK. The system will automatically clean the whole tubing system.

8.1.2 Clean When Shut Down

The tubing system has to be cleaned before shut down the instrument. This step is also automatically performed. Please refer to part **3.16**

8.2 Weekly Maintenance

8.2.1 Surface Maintenance

User should clean the surface of the instrument at least once a week, getting rid of dirty, blood spatters, especially around the probe.

Note: Do not use corrosive acids, alkali or volatile organic solvent (such as acetone, ether and chloroforms) to wipe the surface.

8.2.2 Tubing Maintenance

Use detergent to wash the tubing system at least once a week to ensure no clogs. Steps are as follows:

a. Remove the diluent pipe marked with blue label from the connector in the back panel.

b. At blood analysis page, press MENU to select Prime and pres OK.

c. Repeat the step b. until “No diluent” can be read in the display.

d. Take out the pipe from diluent container and insert it into detergent container and then connect the other end with the diluent connector and repeat step b. until the alarm disappears.

e. 20 minutes later, repeat step a-c.

f. Put the diluent pipe into diluent container again and perform priming 3

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times.

8.2.3 Probe Maintenance

Clean the probe at least once a week. Please refer to part **9.3.1**

8.3 Yearly Maintenance

Yearly maintenance can keep a good performance of the instrument and prolong its life. The maintenance should be performed by engineers authorized. Please contact the customer service office of LABOMED.

8.4 Other Maintenance

If the instrument is left unused for 3 months or it will be shipped, it has to be maintained as follows:

a) Disconnect the diluent pipe and lyse pipe from the back panel. Drain out the liquid inside the pipes.

b) Cover the reagent containers and store them in a stipulated environment.

c) Prime until “No Diluent”, “No Lyse” can be read in the display.

d) Insert the reagent pipes into distilled water.

e) Prime until “No Diluent”, “No Lyse” or “No Detergent” disappears.

f) Press RUN button on the front panel Under Blood analysis page, after one round measurement press **RUN** again.

g) Remove the diluent and lyse pipes and rinse them with distilled water. Dry and pack them.

h) Prime until “No Diluent”, “No Lyse” can be read in the display.

i) Shut down the system refer to part **3.16**

j) Remove the waste pipe and wash it with distilled water. Dry and pack it. Recover all the connectors in the back panel.

k) Remove wires and pack them.

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9. Troubleshooting

9.1 Classification

Generally speaking, troubleshooting consists of the following three situations:

1. Hardware problem.
2. Software problem.
3. Analysis problem.

Hardware and software problems have to be solved only by an authorized engineer. Analysis problem can be solved by user under the help of LABOMED engineers.

9.2 Technical Assistance

If assistance from LABOMED is needed for troubleshooting, please call LABOMED customer service or contact the agent. Details and problem descriptions must be provided when seeking for technical assistance. Details are as follows:

-- The model
-- Serial number and version number.
-- Detailed and clear description of the problem.
-- The Lot No. of reagents (lyse, diluent and detergent).
-- Related data and report.

Problems list and means are given in this part. User can identify the causes according to the warning information and find means according to the troubleshooting provided in the list.

9.3 Means

Problems and means are listed as follows. If no means can be found, user can ask for technical assistance.

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9.3.1 WBC and RBC clogs

If counting time exceeds maximum limit, the system will send alarms and warnings can be read on the display as “WBC CLOG” or “RBC CLOG”.

Means and steps:

a) Press any key in the front panel to stop the alarm.

b) Press Menu, select 1 Maintenance, then select Daily Maintenance, then put a bottle of detergent under the probe and press the Start button.

If the above means is not applicable to serious clogs, the following steps can be performed:

a) Add about 4ml probe detergent into a clean tube.

b) At Blood analysis page, press MENU, select “Daily Maintenance”.

c) Put the tube with probe detergent under the probe (insure the probe reaches the bottom), press the Start button.

If the above means still doesn’t work, solve it by adding probe detergent manually. Steps are as follows:

a) As Figure 41 shows, open the left door.

Figure 41 Open left door

b) After sample priming system stops running, suck probe detergent with an injector as Figure 42 and then inject 3ml detergent into the probe cup.

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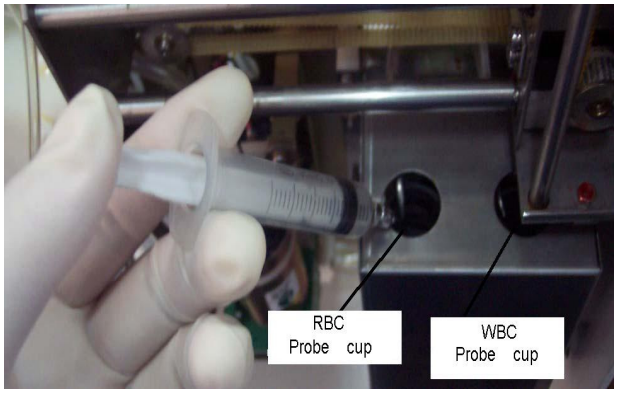

Figure 42 Inject detergent

9.3.2 Abnormal WBC Results

9.3.2.1 Larger Results

Probable causes:

-- abnormal sample.

-- abnormal lyse

-- lyse can't be added.

Means and steps:

-- Replace blood sample (or using medium controls instead) and measure again.

-- If problem can not be solved, remove the lyse pipe marked with red connector on the back panel and then empty the pipe and hang it up.

-- At blood analysis page, press MENU and then select Prime several times until NO LYSE can be read in the display.

-- Replace lyses.

-- At blood analysis page, press MENU and then select Prime several times until the alarm disappears.

-- As for solving the failure of lyse addition, please refer to 9.3.8.

9.3.2.2 Inordinate Results

Probable causes: the filter under the probe cup is jammed.

Means:

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-- As Figure 41 shows, open the left-side door.

-- There are two filters under the probe cup shown as Figure 43.

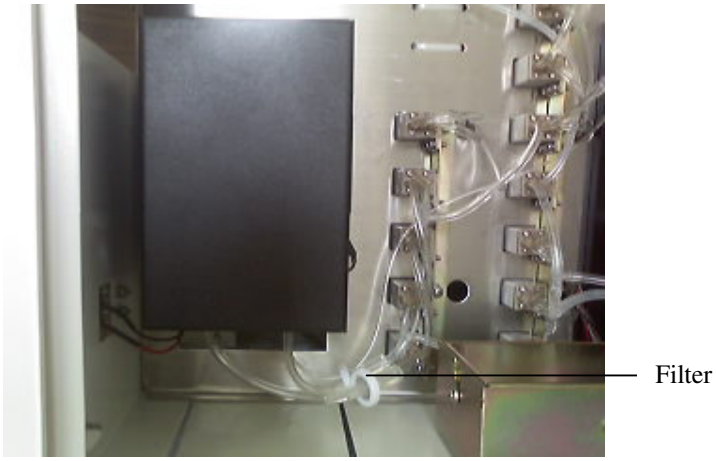

Figure 43 Filters

-- Sip up the liquid in WBC probe cup with syringe.

-- Remove the pipes and take out the filter, examine if there is clog inside. Replace the filter if there is.

If the above method still doesn't work, please contact with LABOMED customer service or its agent.

9.3.3 Bubbles

The system will send alarms if there are bubbles inside WBC or RBC pipes. Means and steps:

-- Press any key to stop the alarm.

-- At blood analysis page, press MENU and then select Prime and press OK.

Fill Dilution first, and fill detergent

9.3.4 Pressure error

"Inordinate pressure" can be read in the display if the system can't supply rating pressure within the set time.

Means and steps:

-- Press any key to stop the alarm.

-- At blood analysis page, press MENU and then select Prime and press OK

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9.3.5 Waste Full

The system will send alarm if the waste container is full.

Probable cause: Waste is full.

Means and steps: Empty the waste container.

9.3.6 No HGB Result

The HGB results is marked with ** or its result is 00, it indicates there is a problem.

Probable cause: bubbles are left in the sample.

Means and steps:

-- At blood analysis page, press MENU and then select Prime and press OK

-- Check if the light in WBC cup is on when measurement.

9.3.7 No Diluent Supply

Probable causes: Diluent runs out or diluent pump fails

Means and steps:

-- Replace diluent

-- At blood analysis page, press MENU and then select Prime and press OK.

9.3.8 No Lyse Supply

Probable causes:

-- Lyse runs out.

-- Lyse sensor is dirty

Means and steps:

-- Press any key to stop the alarm.

-- Replace the lyse

-- At blood analysis page, press MENU and then select Prime and press OK.

9.3.9 No Detergent Supply

Probable causes: Detergent runs out.

Means and steps:

-- Replace detergent.

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-- At blood analysis page, press MENU and then select Prime and press OK.

9.3.10 Time Error

Probable causes: Wrong time setup.

Means and steps:

Please refer to part **4.7.11**

9.3.11 Print Out Fails

Probable causes: No print paper left.

Means and steps

-- Gently press the Printer cover then the cover will open automatically.

-- Place a new roll of print paper onto the standing pole, push the fixer back to loosen it.

-- Pull out a section of the paper and insert it into the slot and then drag the paper out of the slot until the paper's head can reach the little exit in the cover.

-- Close the cover.

Note:

-- Only qualified print paper can be used, otherwise it may lead to printer failure.

-- Please do not open the printer cover, but only when you need to replace the paper replacement or if problems should arise.